

## U. S. ENVIRONMENTAL PROTECTION AGENCY



# PREMANUFACTURE NOTICE

## FOR NEW CHEMICAL SUBSTANCES

When completed, send this form to:

**DOCUMENT CONTROL OFFICER  
OFFICE OF POLLUTION PREVENTION  
AND TOXIC SUBSTANCES, 7407  
U.S. E.P.A. 401 M STREET, SW  
WASHINGTON, D.C. 20460**

**Enter the total number of pages  
in the Premanufacture Notice**

Date of receipt

**AGENCY USE ONLY**

Document control number

EPA case number

## GENERAL INSTRUCTIONS

TS-

- \* You must provide all information requested in this form to the extent that it is known to or reasonably ascertainable by you. Make reasonable estimates if you do not have actual data.**
- \* Before you complete this form, you should read the "Instructions Manual for Premanufacture Notification" (the Instructions Manual is available from the Toxic Substances Control Act (TSCA) Information Service by calling 202-554-1404, or faxing 202-554-5603).**
- \* If a user fee has been remitted for this notice (40 CFR 700.45), indicate in the boxes above the TS-user fee identification number you have generated.**
- Remember, your user fee ID number must also appear on your corresponding fee remittance, which is sent to: EPA, HQ Accounting Operations Branch (PM-266), P.O. 360399M, Pittsburgh, PA 15251-6399, Attn: TSCA User Fee.**

## Part I -- GENERAL INFORMATION

**You must provide the currently correct Chemical Abstracts (CA) Name of the new chemical substance, even if you claim the identity as confidential. You may authorize another person to submit chemical identity information for you, but your submission will not be complete and the review will not begin until EPA receives this information. A letter in support of your submission should reference your TS user fee identification number. You must submit an original and two copies of this notice including all test data. If you claimed any information as confidential, a single sanitized copy must also be submitted.**

## Part II – HUMAN EXPOSURE AND ENVIRONMENTAL RELEASE

If there are several manufacture, processing, or use operations to be described in Part II, sections A and B of this notice, reproduce the sections as needed.

### Part III – LIST OF ATTACHMENTS

Attach additional sheets if there is not enough space to answer a question fully. Label each continuation sheet with the corresponding section heading. In Part III, list these attachments, any test data or other data and any optional information included in the notice.

### OPTIONAL INFORMATION

**You may include any information that you want EPA to consider in evaluating the new substance. On page 11 of this form, space has been provided for you to describe pollution prevention and recycling information you may have regarding the new substance.**

So-called "binding" boxes are included throughout this form for you to indicate your willingness to be bound to certain statements you make in this notice, such as use, production volume, protective equipment . . . This option is intended to reduce delays that routinely accompany the development of consent orders or Significant New Use Rules. Except in the case of exemption applications (such as TMEA, LVE, LOREX) where certain information provided in such notification is binding on the submitter when the Agency approves the exemption application, checking a binding box in this notice does not by itself prohibit the submitter from later deviating from the information (except chemical identity) reported in the form.

## CONFIDENTIALITY CLAIMS

**You may claim any information in this notice as confidential. To assert a claim on the form, mark (X) the confidential box next to the information that you claim as confidential. To assert a claim in an attachment, circle or bracket the information you claim as confidential. If you claim information in the notice as confidential, you must also provide a sanitized version of the notice, (including attachments). For additional instructions on claiming information as confidential, read the Instructions Manual.**

☐ Mark (X) if any information in this notice is claimed as confidential.

## TEST DATA AND OTHER DATA

You are required to submit all test data in your possession or control and to provide a description of all other data known to or reasonably ascertainable by you, if these data are related to the health and environmental effects of the manufacture, processing, distribution in commerce, use, or disposal of the new chemical substance. Standard literature citations may be submitted for data in the open scientific literature. Complete test data (written in English), not summaries of data, must be submitted if they do not appear in the open literature. You should clearly identify whether test data is on the substance or on an analog. Also, the chemical composition of the tested material should be characterized. Following are examples of test data and other data. Data should be submitted according to the requirements of §720.50 of the Premanufacture Notification Rule (40 CFR Part 720).

**Test Data** (Check Below any included in this notice)

- |                                  |                          |     |   |                          |     |
|----------------------------------|--------------------------|-----|---|--------------------------|-----|
| • Environmental fate data        | <input type="checkbox"/> | Yes | • Other data  | <input type="checkbox"/> | Yes |
| • Health effects data            | <input type="checkbox"/> | Yes | Risk assessments  |                          |     |
| • Environmental effects data     | <input type="checkbox"/> | Yes | Structure/activity relationships                            |                          |     |
| • Physical/Chemical Properties * | <input type="checkbox"/> | Yes | Test data not in the possession or control of the submitter |                          |     |

\*A physical and chemical properties worksheet is located on the last page of this form.

**TYPE OF NOTICE** (Check Only One)

- ☐ PMN (Premanufacture Notice)
- ☐ INTERMEDIATE PMN (submitted in sequence with final product PMN)
- ☐ SNUN (Significant New Use Notice)
- ☐ TMEA (Test Marketing Exemption Application)
- ☐ LVE (Low Volume Exemption) @ 40 CFR 723.50 (c)(1)
- ☐ LOREX (Low Release/Low Exposure Exemption) @ 723.50(c)(2)
- ☐ LVE Modification ☐ LOREX Modification

IS THIS A CONSOLIDATED PMN? ☐ Yes

# of chemicals \_\_\_\_\_  
(Prenotice Communication # required, enter # on page 3)

Public reporting burden for this collection of information is estimated to average 110 hours per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, PM-223, U.S. Environmental Protection Agency, 401 M. St., S.W., Washington, D.C. 20460; and to the Office of Management and Budget, Paperwork Reduction Act (2070-0012), Washington, D.C. 20503.

## CERTIFICATION

I certify that to the best of my knowledge and belief:

1. The company named in Part I, section A, subsection 1a of this notice form intends to manufacture or import for a commercial purpose, other than in small quantities solely for research and development, the substance identified in Part I, Section B.
2. All information provided in this notice is complete and truthful as of the date of submission.
3. I am submitting with this notice all test data in my possession or control and a description of all other data known to or reasonably ascertainable by me as required by §720.50 of the Premanufacture Notification Rule.

### Additional Certification Statements:

If you are submitting a PMN, Intermediate PMN, Consolidated PMN, or SNUN, check the following **user fee** certification statement that applies:

- ☐ The Company named in Part I, Section A has remitted the fee of \$2500 specified in 40 CFR 700.45 (b), or
- ☐ The Company named in Part I, Section A has remitted the fee of \$1000 for an Intermediate PMN (defined @ 40 CFR 700.43) in accordance with 40 CFR 700.45(b), or
- ☐ The Company named in Part I, Section A is a small business concern under 40 CFR 700.43 and has remitted a fee of \$100 in accordance with 40 CFR 700.45 (b).

If you are submitting a **low volume exemption (LVE)** application in accordance with 40 CFR 723.50 (c) (1) or a **Low release and low exposure exemption (LoREX)** application in accordance with 40 CFR 723.50 (c) (2), check the following certification statements:

- ☐ The manufacturer submitting this notice intends to manufacture or import the new chemical substance for commercial purposes, other than in small quantities solely for research and development, under the terms of 40 CFR 723.50.
- ☐ The manufacturer is familiar with the terms of this section and will comply with those terms; and
- ☐ The new chemical substance for which the notice is submitted meets all applicable exemption conditions.
- ☐ If this application is for an LVE in accordance with 40 CFR 723.50 (c)(1), the manufacturer intends to commence manufacture of the exempted substance for commercial purposes within 1 year of the date of the expiration of the 30 day review period.

The accuracy of the statements you make in this notice should reflect your best prediction of the anticipated facts regarding the chemical substance described herein. Any knowing and willful misinterpretation is subject to criminal penalty pursuant to 18 USC 1001.

Confidential

Signature and title of Authorized Official (Original Signature Required)

Date

Signature of agent - (if applicable)

Date

# Part I -- GENERAL INFORMATION

## Section A -- SUBMITTER IDENTIFICATION

Confidential

Mark (X) the "Confidential" box next to any subsection you claim as confidential.

1a. Person Submitting Notice (in U.S.)

Name of authorized official

Position

Company

Mailing address (number and street)

City, State, ZIP Code

b. Agent (if applicable)

Name of authorized official

Position

Company

Mailing address (number and street)

City, State, ZIP Code

Telephone

Area Code

Number

c. If you are submitting this notice as part of a joint submission, mark (X) this box. ☐

Joint Submitter (if applicable)

Name of authorized official

Position

Company

Mailing address (number and street)

City, State, ZIP Code

Telephone

Area Code

Number

2. Technical Contact (in U.S.)

Name

Position

Company

Mailing address (number and street)

City, State, ZIP Code

Telephone

Area Code

Number

3. If you have had a prenotice communication (PC) concerning this notice and EPA assigned a PC Number to the notice, enter the number.

Mark (X) if none ☐

4. If you previously submitted an exemption application for the chemical substance covered by this notice, enter the exemption number assigned by EPA. If you previously submitted a PMN for this substance enter the PMN number assigned by EPA (i.e. withdrawn or incomplete).

Mark (X) if none ☐

5. If you have submitted a notice of Bona fide intent to manufacture or import for the chemical substance covered by this notice, enter the notice number assigned by EPA.

Mark (X) if none ☐

6. Type of Notice -- Mark (X)

1.

☐

Manufacture Only

2.

☐

Import Only

3.

☐

Both

☐

Binding Option Mark (x)

☐

Binding Option Mark (x)

## Part I -- GENERAL INFORMATION -- Continued

### Section B -- CHEMICAL IDENTITY INFORMATION:

You must provide a currently correct Chemical Abstracts (CA) name of the substance based on the ninth Collective Index (9CI) of CA nomenclature rules and conventions.

Mark (X) the "Confidential" box next to any item you claim as confidential.

Complete either item 1 (Class 1 or 2 substances) or 2 (Polymers) as appropriate. Complete all other items.

If another person will submit chemical identity information for you (for either item 1 or 2), mark (X) the box at the right.

Identify the name, company, and address of that person in a continuation sheet.

☐

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1. Class 1 or 2 chemical substances (for definitions of class 1 and class 2 substances, see the Instructions Manual)

a. Class of substance -- Mark (X)      1 ☐ Class 1    or    2 ☐ Class 2

b. Chemical name (Currently correct Chemical Abstracts (CA) Name that is consistent with TSCA Inventory listings for similar substances. For Class 1 substances a CA Index Name must be provided. For Class 2 substances either a CA Index Name or CA Preferred Name must be provided, whichever is appropriate based on CA 9CI nomenclature rules and conventions.)

c. Please identify which method you used to develop or obtain the specified chemical identity information reported in this notice: (check one).

☐

Method 1 (CAS Inventory Expert Service - a copy of the Identification report obtained from the CAS Inventory Expert Service must be submitted as an attachment to this notice)

☐

Method 2 (Other Source)

d. Molecular formula and CAS Registry Number (if a number already exists for the substance)

CAS #

e. For a class 1 substance, provide a complete and correct chemical structure diagram. For a class 2 substance -- (1) List the immediate precursor substances with their respective CAS Registry Numbers. (2) Describe the nature of the reaction or process. (3) Indicate the range of composition and the typical composition (where appropriate). (4) Provide a correct representative or partial chemical structure diagram, as complete as can be known, if one can be reasonably ascertained.

☐

Mark (X) this box if you attach a continuation sheet.

# Part I -- GENERAL INFORMATION -- Continued

## Section B -- CHEMICAL IDENTITY INFORMATION -- Continued

### 2. Polymers (For a definition of polymer, see the Instructions Manual.)

Confidential

- a. Indicate the number-average weight of the lowest molecular weight composition of the polymer you intend to manufacture. Indicate maximum weight percent of low molecular weight species (not including residual monomers, reactants, or solvents) below 500 and below 1,000 absolute molecular weight of that composition.

Describe the methods of measurement or the basis for your estimates: GPC ☐ Other ☐ : (Specify) \_\_\_\_\_

i) lowest number average molecular weight: \_\_\_\_\_

ii) maximum weight % below 500 molecular weight: \_\_\_\_\_

iii) maximum weight % below 1000 molecular weight: \_\_\_\_\_

☐ Mark (X) this box if you attach a continuation sheet.

- b. You must make separate confidentiality claims for monomer or other reactant identity, composition information, and residual information. Mark (X) the "Confidential" box next to any item you claim as confidential.

- (1) -- Provide the specific chemical name and CAS Registry Number (if a number exists) of each monomer or other reactant used in the manufacture of the polymer.
- (2) -- Mark (X) this column if entry in column (1) is confidential.
- (3) -- Indicate the typical weight percent of each monomer or other reactant in the polymer.
- (4) -- Mark (X) the identity column if you want a monomer or other reactant used at two weight percent or less to be listed as part of the polymer description on the TSCA Chemical Substance Inventory.
- (5) -- Mark (X) this column if entries in columns (3) and (4) are confidential.
- (6) -- Indicate the maximum weight percent of each monomer or other reactant that may be present as a residual in the polymer as manufactured for commercial purposes.
- (7) -- Mark (X) this column if entry in column (6) is confidential.

Monomer or other reactant and CAS Registry Number (1)	Confidential (2)	Typical composition (3)	Identity Mark (X) (4)	Confidential (5)	Maximum residual (6)	Confidential (7)
		%			%	
		%			%	
		%			%	
		%			%	
		%			%	
		%			%	
		%			%	

☐ Mark (X) this box if you attach a continuation sheet.

- c. Please identify which method you used to develop or obtain the specified chemical identity information reported in this notice. (check one).

☐ Method 1 (CAS Inventory Expert Service - a copy of the identification report obtained from CAS Inventory Expert Service must be submitted as an attachment to this notice)

☐ Method 2 (other source)

- d. The currently correct Chemical Abstracts (CA) name for the polymer that is consistent with TSCA Inventory listings for similar polymers.

- e. Provide a correct representative or partial chemical structure diagram, as complete as can be known, if one can be reasonably ascertained.

☐ Mark (X) this box if you attach a continuation sheet.

## Part I -- GENERAL INFORMATION -- Continued

### Section B -- CHEMICAL IDENTITY INFORMATION -- Continued

#### 3. Impurities

- (a) -- Identify each impurity that may be reasonably anticipated to be present in the chemical substance as manufactured for commercial purposes. Provide the CAS Registry Number if available. If there are unidentified impurities, enter "unidentified."  
 (b) -- Estimate the maximum weight % of each impurity. If there are unidentified impurities, estimate their total weight %.

Impurity and CAS Registry Number (a)	Maximum percent (b)	Confidential
	%	
	%	
	%	
	%	
	%	
	%	
	%	
	%	

☐ Mark (X) this box if you attach a continuation sheet.

#### 4. Synonyms -- Enter any chemical synonyms for the new chemical substance identified in subsection 1 or 2.

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☐ Mark (X) this box if you attach a continuation sheet.

#### 5. Trade identification -- List trade names for the new chemical substance identified in subsection 1 or 2.

☐ Mark (X) this box if you attach a continuation sheet.

#### 6. Generic chemical name -- If you claim chemical identity as confidential, you must provide a generic chemical name for your substance that reveals the specific chemical identity of the new chemical substance to the maximum extent possible. Refer to the TSCA Chemical Substance Inventory, 1985 Edition, Appendix B for guidance on developing generic names.

☐ Mark (X) this box if you attach a continuation sheet.

#### 7. Byproducts -- Describe any byproducts resulting from the manufacture, processing, use, or disposal of the new chemical substance. Provide the CAS Registry Number if available.

Byproduct (1)	CAS Registry Number (2)	Confidential

☐ Mark (X) this box if you attach a continuation sheet.

## Part I -- GENERAL INFORMATION -- Continued

### Section C -- PRODUCTION, IMPORT, AND USE INFORMATION:

Mark (X) the "Confidential" box next to any item you claim as confidential.

**1. Production volume** -- Estimate the **maximum** production volume during the first 12 months of production. Also estimate the maximum production volume for any consecutive 12-month period during the first three years of production. Estimates should be on 100% new chemical substance basis. *For a Low Volume Exemption application, if you choose to have your notice reviewed at a lower production volume than 10,000 kg/yr, specify the volume and mark (x) in the binding box. If granted, you are bound to this volume..*

Maximum first 12-month production (kg/yr) (100% new chemical substance basis)	Maximum 12-month production (kg/yr) (100% new chemical substance basis)	Confidential	Binding Option Mark (x)

**2. Use Information** -- You must make separate confidentiality claims for the description of the category of use, the percent of production volume devoted to each category, the formulation of the new substance, and other use information. Mark (X) the "Confidential" Box next to any item you claim as confidential.

- a. (1) -- Describe each intended category of use of the new chemical substance by function and application.  
 (2) -- Mark (X) this column if entry in column (1) is confidential business information (CBI).  
 (3) -- Indicate your willingness to have the information provided in column (1) binding.  
 (4) -- Estimate the percent of total production for the first three years devoted to each category of use.  
 (5) -- Mark (X) this column if entry in column (4) is confidential business information (CBI).  
 (6) -- Estimate the percent of the new substance as formulated in mixtures, suspensions, emulsions, solutions, or gels as manufactured for commercial purposes at sites under your control associated with each category of use.  
 (7) -- Mark (X) this column if entry in column (6) is confidential business information (CBI).  
 (8) -- Indicate % of product volume expected for the listed "use" sectors. Mark more than one box if appropriate. Mark (X) to indicate your willingness to have the use type provided in (8) binding.  
 (9) -- Mark (X) this column if entry(ies) in column (8) is (are) confidential business information (CBI).

Category of use (1) (by function and application i.e. a dispersive dye for finishing polyester fibers)	CBI (2)	Binding Option Mark (x) (3)	Production % (4)	CBI (5)	% in Formulation (6)	CBI (7)	% of substance expected per use (8)					CBI (9)
							Site-limited	Consumer	Industrial	Commercial	Binding Option	
			%		%							
			%		%							
			%		%							
			%		%							
			%		%							
			%		%							
			%		%							

\*If you have identified a "consumer" use, please provide on a continuation sheet a detailed description of the use(s) of this chemical substance in consumer products. In addition include estimates of the concentration of the new chemical substance as expected in consumer products and describe the chemical reactions by which this substance loses its identity in the consumer product.

☐ Mark (X) this box if you attach a continuation sheet.

b. Generic use description

If you claim any category of use description in subsection 2a as confidential, enter a generic description of that category. Read the **Instructions Manual** for examples of generic use descriptions.

☐ Mark (X) this box if you attach a continuation sheet.

**3. Hazard Information** -- Include in the notice a copy of reasonable facsimile of any hazard warning statement, label, material safety data sheet, or other information which will be provided to any person who is reasonably likely to be exposed to this substance regarding protective equipment or practices for the safe handling, transport, use, or disposal of the new substance. List in part III hazard information you include.

☐ Mark (X) this box if you attach hazard information.

Binding Option Mark (x)